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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Ex parte DARREN A. JANZIG, CARL D. WAHLSTRAND,
ROBERT M. SKIME, MARK S. LENT,
KEITH A. MIESEL, and JAMES E. CABAK

Appeal 2009-005345
Application 10/731,699
Technology Center 3700

Decided: April 30, 2010

Before: WILLIAM F. PATE III, KEN B. BARRETT, and
FRED A. SILVERBERG, *Administrative Patent Judges*.

PATE III, *Administrative Patent Judge*.

DECISION ON APPEAL

STATEMENT OF CASE

Appellants appeal under 35 U.S.C. § 134 from a rejection of claims 1, 3-11, 13-15 and 17-25. App. Br. 3. We have jurisdiction under 35 U.S.C. § 6(b).

The claims are directed to implantable medical device ("IMD").
Claim 1, reproduced below, is illustrative of the claimed subject matter:

1. An implantable medical device comprising:

at least two modules, each of the modules comprising a
respective one of at least two housings;

a coupling module coupled to each of the modules, the
coupling module defining at least one lumen between the
housings; and

an overmold that at least partially encapsulates each of
the housings and the coupling module,

wherein the coupling module permits motion of the two
modules along at least one axis of motion.

REFERENCES

The prior art relied upon by the Examiner in rejecting the claims on
appeal is:

Lynch	US 4,934,368	Jun. 19, 1990
Hirschberg	US 5,312,440	May 17, 1994
Meltzer	US 5,645,586	Jul. 8, 1997
Wahlstrand	US 7,212,864 B2	May 1, 2007

REJECTIONS

Claim 25 stands rejected under 35 U.S.C. § 102(b) as being
anticipated by Lynch. Ans. 3.

Claims 7-11, 14, 15, 17 and 20-23 stand rejected under 35 U.S.C.
§ 102(b) as being anticipated by Hirschberg. Ans. 3.

Claims 1, 3-6 and 24 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Lynch. Ans. 3.

Claims 13, 18 and 19 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Hirschberg¹. Ans. 4.

Claims 7, 8, 19 and 25 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Meltzer. Ans. 4.

Claim 1 stands rejected under the judicially-created doctrine of obviousness-type double patenting as being unpatentable over claim 1 of U.S. Patent number 7,212,864. Ans. 5.

OPINION

The rejection of claim 25 as being anticipated by Lynch is reversed.

Appellants contend that the Examiner's finding that Lynch inherently discloses hermetic sealing of the coupling module because Lynch discloses an "environmental" seal within the body, is erroneous because an "environmental" seal within the body, does not necessarily require "hermetic" sealing. App. Br. 7-10.

"To establish inherency, the extrinsic evidence must make clear that the missing descriptive matter is necessarily present in the thing described in the reference. Inherency, however, may not be established by probabilities or possibilities. The mere fact that a certain thing may result from a given set of circumstances is not sufficient." *In re Robertson*, 169 F.3d 743, 745 (Fed. Cir. 1999) (citations and internal quotations omitted).

Appellants' Specification discusses the ability to provide protection within the body without necessarily providing a "hermetic" seal. Spec. p. 14,

¹ Claim 12 has been cancelled. App. Br. 14.

para. [0061]. Similarly, Lynch describes certain structures 6 as “hermetically” sealed, while describing other seals 13, 14 as “environmental.” Cf. Lynch col. 6, ll. 20-22, col. 7, ll. 46-47. Lynch goes on to say that seals 13, 14 are exceptionally resistant against moisture, but Lynch does not describe these seals as “hermetic.” Col. 8, ll. 1-2. The ability to exclude “moisture” does not necessarily make a seal “hermetic.” There is no evidence to support the Examiner’s contention that every seal within the body must be hermetic. Ans. 5-6, 7. This finding is contrary to both the teachings of the Specification and the prior art. If the structures within seals 13, 14 required a less than hermetic level of protection from the environment, hermetic sealing of those structures would not be necessary. Since Lynch is silent regarding that subject we must conclude that the hermetic sealing of Lynch’s leads 3, read as the claimed “coupling module” is not necessarily present, and therefore not an inherent feature of Lynch as was found by the Examiner.

Appellants’ and the Examiner’s discussion of “teaching away” (App. Br. 8; Ans. 5) is not relevant to a rejection under 35 U.S.C. § 102(b). *See Seachange Intern., Inc. v. C-COR, Inc.* 413 F.3d 1361, 1380 (Fed. Cir. 2005). Nor is Appellants’ and the Examiner’s discussion of the reasons why or why not one would incorporate hermetic seals into Lynch’s device. Ans. 6; App. Br. 10.

The rejection of claims 7-11, 14, 15, 17 and 20-23 as being anticipated by Hirschberg is reversed.

For reasons similar to those discussed above regarding the rejection of claim 25 as being anticipated by Lynch, the Examiner also erred by finding

that, due to its presence in the body, Hirschberg's lead 9, read as the claimed "coupling module," was inherently "hermetically fixed" to the housing 15 and the defibrillator 1, read as the claimed " housings."

The rejection of claims 1, 3-6 and 24 as being unpatentable over Lynch is reversed

The Examiner opines that based upon the fact that Lynch's cuff 2 may be sealed to the lead 3 with a final dip coat, it would have been obvious to apply a dip coat to both the case 12 and the lead 3. Ans. 3-4; Lynch col. 8, ll. 32-35. Claim 1 requires that an overmold at least partially encapsulates "each" of the housing and the coupling module. The Examiner does not specify what structure of Lynch is regarded as the claimed housings and coupling modules. Based upon the Examiner's analysis of claim 25, Lynch's case 12 and nerve cuff 2 are read as the claimed modules comprising respective housings, and leads 3 are read as the claimed "coupling module." Thus, to meet the claim Lynch's dip coat, read as the claimed "overmold" would need to at least partially encapsulate case 12, nerve cuff 2 and leads 3. Lynch's device is designed so that nerve cuffs 2 may be selectively placed at various distances from the master circuitry case 12. *See e.g.*, Fig. 1. Additionally, an important feature of Lynch's invention is the ability to replace leads without replacing the entire system. Col. 3, ll. 40-51. Providing a dip coat over Lynch's case 12, leads 3 and nerve cuff 2 would restrict the flexibility of Lynch's system and might prevent the separability of the leads. Since there would have been no rationale basis to destroy this functionality of Lynch, the Examiner has failed to articulate any reason with a rationale underpinning to support the conclusion of obviousness. App. Br. 16-18. *See*

In re Kahn, 441 F.3d 977, 988 (Fed. Cir. 2006) (there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness), cited with approval in *KSR International Co. v. Teleflex Inc.*, 550 U.S. 398, 418 (2007).

The rejection of claims 13, 18 and 19 as being unpatentable over Hirschberg is reversed.

Contrary to the Examiner's finding regarding the rejection of claim 7 as being anticipated by Hirschberg, in the rejection of claims 13, 18 and 19 the Examiner indicates that hermetic fixation is not disclosed by Hirschberg but that it would have been an obvious variant. Ans. 4. Claims 13, 18 and 19 do not further limit features related to hermetic fixation. Only parent claim 7 contains this limitation. Neither the Examiner nor the Appellants adequately addresses the issue of whether hermetic fixation would have been an obvious modification to Hirschberg. App. Br. 11-12, 15-16; Ans. 8. We will not assume that the Examiner intended claim 7 to be rejected in the alternative under 35 U.S.C. § 103(a) as being unpatentable over Hirschberg. Appellants have not had a fair opportunity to react to such a rejection. We therefore do not reach the issue of whether hermetic fixation would have been an obvious modification to Hirschberg's device. Instead, we reverse the rejection of claims 13, 18 and 19 as being unpatentable over Hirschberg because the examiner erred in determining the scope and content of the prior art with respect to parent claim 7, as indicated above.

Regarding the rejections discussed below, we find that the following enumerated facts are supported by at least a preponderance of the evidence.

Ethicon, Inc. v. Quigg, 849 F.2d 1422, 1427 (Fed. Cir. 1988) (explaining the general evidentiary standard for proceedings before the Office).

1. Rigidity of an implantable medical device (“IMD”) housing is a problem perceived by the inventors of the claimed subject matter. Spec. 2, para. [0004].
2. Meltzer discloses an implantable medical device that is adapted to conform to the contour of an implantation site and/or to flex in compliance with movement at such an implantation site. Col. 1, ll. 6-10. Meltzer acknowledges the desirability of manufacturing low-profile implants. Col. 1, ll. 56-57.
3. Appellants recognize that in order to avoid potentially harmful interactions between the components of an IMD and bodily fluids, IMD housings are typically hermetically sealed. Spec. 2, para. [0004].
4. Meltzer discloses an IMD housing 38, for a defibrillator or other device. Col. 3, ll. 5-9, 55-60. The housing 38, which may be constructed from a biocompatible material such as titanium or stainless steel, includes three segments 23, 24, 25 interconnected by, and pivotable about, hinge axes 27, 28. The hinge axes are constructed so as not to compromise the integrity of the enclosure seal, which is typically made by welding the half shells together to form a hermetic seal. Col. 3, ll. 19-51; fig. 2.
5. According to one embodiment described by Meltzer, a hinge arrangement including a transverse cylinder 34 within a transverse channel 35 is employed to electrically connect segments 31, 32 of the housing while maintaining the integrity of the housing seal. Col. 3, l. 65 – col. 4, l. 35; fig. 3.

6. In an alternative embodiment Meltzer discloses that an encapsulated interconnect cable 43, such as a ribbon cable, may be used at the hinge axis to mechanically and electrically interconnect the segments. Col. 4, ll. 29-30; fig. 4.
7. Meltzer further discloses that either the housing segments or the entire housing may be coated with a biocompatible polymer, such as silicone rubber for sealing the device. Col. 4, ll. 45-48
8. In another alternative embodiment Meltzer discloses that a highly compliant flexible housing 50, 51 can form a sealed enclosure for various electrical components of the device. Col. 4, ll. 49-60; fig. 5.
9. Meltzer teaches that it is known to include a battery 55 in an IMD.

The rejection of claims 7, 8, 19 and 25 as being unpatentable over Meltzer is affirmed.

Regarding the Examiner's rejection of claims 7, 8, 19 and 25, the Examiner incorrectly found that Meltzer fails to disclose "a coupling module that defines at least one lumen between the first and second housings." Ans. 4-5. It is readily apparent from Meltzer that hinge 33 is a "coupling module" that defines, by way of transverse cylinder 34, "at least one lumen between the first and second housings," 31, 32, wherein at least one of the housings contains control electronics. Facts 4 and 5. Meltzer's encapsulated interconnect, or ribbon, cable would also define a "lumen between the first and second housings." Fact 6. Both the embodiment depicted in Figure 3 of Meltzer and the embodiment depicted in Figure 4 of Meltzer would therefore have anticipated claim 25. Since anticipation is the epitome of obviousness the Examiner did not err in concluding that the subject matter of claim 25

would have been obvious. *In re Baxter Travenol Labs* 952 F.2d 388, 390-91 (Fed. Cir. 1991).

Appellants argue claims 7, 8 and 19 as a group. Claim 7 is representative. 37 C.F.R. § 41.37(c)(1)(vii). Appellants' conclusion that the rejection of claim 7 should be withdrawn because the Examiner failed to identify metal as a known material in the prior art is unpersuasive. It is readily apparent from Meltzer that metals, such as titanium and stainless steel are known in the art. *See* Fact 4. As Appellants point out, Meltzer only describes these materials as materials that may be used for constructing the housing 38 and does not describe a specific embodiment wherein those materials are used in the connector member, hinge 33. Including a metal defining a lumen in the connecting member is a modification that would have been obvious to one having ordinary skill in the art. While Meltzer prefers polymetric compositions for the connector member, one of ordinary skill in the art would recognize that known metallic compositions may also be used in the connecting member in order to, for example, to physically protect or electronically shield, the cables contained therein. Thus the Examiner did not err in concluding that the subject matter of claim 7 would have been obvious to one having ordinary skill in the art.

The rejection of claim 1 under the judicially-created doctrine of obviousness-type double patenting is reversed.

Appellants correctly point out that, if the Examiner has assessed the differences between the claims alleged to be patentably indistinct, those findings have not been made explicit in the Examiner's rejection. App. Br. 21-22; Ans. 5. Under that facet of the doctrine of double patenting, we must

direct our inquiry to whether the claimed invention in the application for the second patent would have been obvious from the subject matter of the claims in the first patent, in light of the prior art. *Carman Industries Inc. v. Wahl*, 724 F.2d 932, 940 (Fed. Cir. 1983). The examiner bears the initial burden of factually supporting any prima facie conclusion of obviousness. The key to supporting any prima facie conclusion of obviousness under 35 U.S.C. § 103 is the clear articulation of the reason(s) why the claimed invention would have been obvious. The Court in *KSR International Co. v. Teleflex Inc.*, 550 U.S. 398, 418 (2007) noted that the analysis supporting a rejection under 35 U.S.C. § 103 should be made explicit. The Federal Circuit has stated that “rejections on obviousness grounds cannot be sustained by mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness.” *In re Kahn*, 441 F.3d 977, 988 (Fed. Cir. 2006), cited with approval in *KSR*, 550 U.S. at 418. Since the Examiner has not made of record any analysis, the Examiner has failed to articulate any reasoning with a rational underpinning to support the legal conclusion of obviousness. Ans. 5.

Pursuant to our authority under 37 C.F.R. § 41.50(b), we enter a new ground of rejection of claims 1, 3-5, 9, 11, and 21-24 under 35 U.S.C. § 102(b) as being anticipated by Meltzer.

Meltzer discloses each and every limitation of claims 1, 3-5, 9, 11, and 21-24. Facts 2 and 4-8. Regarding claim 1, as noted above, Meltzer’s encapsulated interconnect, or ribbon, defines a “lumen between the housings.” See Fact 6. Both the biocompatible polymer coating, or the sealed

enclosure, are reasonably read as “an overmold that at least partially encapsulates each of the housings and coupling module.” *See* Facts 7 and 8. Regarding claims 3, 4, 9, 11, 23, and 24 ribbon cables, an example of which is illustrated in Figure 5, although not discussed in detail by Meltzer, are known to define “at least two lumens” having a “circular cross-sectional shape” and “a conductor passing through the lumen.” Regarding claim 22, when used as a hinge, they include “at least one bend.” Regarding claim 5, a defibrillator is, or includes, “a control module containing electronic components.” *See* Fact 4. Regarding claim 21, Meltzer discloses the coupling module “fixedly coupled to portions of the housings that are adjacent one another.” Fact 4.

Pursuant to our authority under 37 C.F.R. § 41.50(b), we enter a new ground of rejection of claims 6, 17, 18, and 20 under 35 U.S.C. § 103(a) as being unpatentable over Meltzer.

Regarding claim 6, Meltzer acknowledges the desirability of making low profile implants and suggests making implants that conform to the contours of the implantation site. Fact 2. In light of this suggestion, it would have been obvious to one having ordinary skill in the art to select the appropriate dimensions to predictably conform to the implantation site. Thus, providing an IMD with a maximum thickness of between 4 and 8 millimeters would have been obvious to one having ordinary skill in the art.

Regarding claims 17, 18, and 20 Meltzer demonstrates that titanium, weld joints, and batteries are known in the art. *See* Facts 4 and 9. It would have been obvious to one of ordinary skill in the art to select the appropriate material, fastening method and power supply, respectively. The use of these

elements amounts to no more than the predictable use of prior art elements according to their known functions and would have been obvious to one having ordinary skill in the art.

The Board of Patent Appeals and Interferences is a review body, rather than a place of initial examination. We have made a rejection above under 37 C.F.R. § 41.50(b) based on the applied prior art references. However, we have not reviewed the remaining claims to the extent necessary to determine whether these claims are unpatentable over the applied prior art references and other patents cited in the record. We leave it to the instant Examiner to determine the appropriateness of any further rejections based on these references.

DECISION

The rejection of claim 25 as being anticipated by Lynch is reversed.

The rejection of claims 7-11, 14, 15, 17 and 20-23 as being anticipated by Hirschberg is reversed.

The rejection of claims 1, 3-6 and 24 as being unpatentable over Lynch is reversed.

The rejection of claims 13, 18 and 19 as being unpatentable over Hirschberg is reversed.

The rejection of claims 7, 8, 19 and 25 as being unpatentable over Meltzer is affirmed.

The rejection of claim 1 under the judicially-created doctrine of obviousness-type double patenting is reversed.

Pursuant to our authority under 37 C.F.R. § 41.50(b), we enter new grounds of rejection of claims 1, 3-5, 9, 11, and 21-24 under 35 U.S.C. § 102(b) as being anticipated by Meltzer.

Pursuant to our authority under 37 C.F.R. § 41.50(b), we enter new grounds of rejection of claims 6, 17, 18, and 20 under 35 U.S.C. § 103(a) as being unpatentable over Meltzer.

FINALITY OF DECISION

Regarding the affirmed rejection(s), 37 C.F.R. § 41.52(a)(1) provides “Appellant may file a single request for rehearing within two months from the date of the original decision of the Board.”

In addition to affirming the Examiner's rejections of one or more claims, this decision contains new grounds of rejection pursuant to 37 C.F.R. § 41.50(b) (2008). 37 C.F.R. § 41.50(b) provides “[a] new ground of rejection pursuant to this paragraph shall not be considered final for judicial review.”

37 C.F.R. § 41.50(b) also provides that Appellant, WITHIN TWO MONTHS FROM THE DATE OF THE DECISION, must exercise one of the following two options with respect to the new grounds of rejection to avoid termination of the appeal as to the rejected claims:

(1) *Reopen prosecution.* Submit an appropriate amendment of the claims so rejected or new evidence relating to the claims so rejected, or both, and have the matter reconsidered by the Examiner, in which event the proceeding will be remanded to the Examiner. . . .

(2) *Request rehearing.* Request that the proceeding be reheard under § 41.52 by the Board upon the same record. . . .

Should Appellants elect to prosecute further before the Examiner pursuant to 37 C.F.R. § 41.50(b)(1), in order to preserve the right to seek review under 35 U.S.C. §§ 141 or 145 with respect to the affirmed rejection, the effective date of the affirmance is deferred until conclusion of the prosecution before the Examiner unless, as a mere incident to the limited prosecution, the affirmed rejection is overcome.

If Appellants elect prosecution before the Examiner and this does not result in allowance of the application, abandonment or a second appeal, this case should be returned to the Board of Patent Appeals and Interferences for final action on the affirmed rejection, including any timely request for rehearing thereof.

No time period for taking any subsequent action in connection with this appeal may be extended under 37 C.F.R. § 1.136(a). See 37 C.F.R. § 1.136(a)(1)(iv) (2007).

AFFIRMED-IN-PART; § 41.50(b)

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